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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,018	06/30/2006	Akito Yasuhara	Q92007	2970

23373 7590 04/01/2010

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EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
04/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/562,018	YASUHARA ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47,50-53 and 56-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47,50-53 and 56-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Rejection

The Status of Claims

Claims 1-47,50-53,and 56-60 are pending.

Claims 1-47,50-53,and 56-60 are rejected.

Priority

In order to correct the priority in the previous office action, it is noted that this application is a 371 of PCT/JP04/09398(06/25/2004), which has foreign priority documents, Japan 2003-181930 (06/26/2003) and Japan 2003-373511(10/31/2003), and Japan 2004-128663(04/23/2004).

Objection

The objection of Claims 1-59 is withdrawn in the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection Claims 1-57 under 35 U.S.C. 112, second paragraph, has been withdrawn due to the modification of the claims; however, the rejection of claim 59 has been maintained due to applicants' failure to modify the claim. Furthermore, there are still some issues present in the claim 18 and 47.

In claims 18 and 47, the phrase " represents a hydrogen atom " is recited. This is vague and indefinite because the claims do not describe the variable for the phrase " represents a hydrogen atom " . Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 1-59 under 35 U.S.C. 112, first paragraph, has been withdrawn due to the modification of the claims.

In view of the revised claims, the following double patenting rejection deems necessary:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

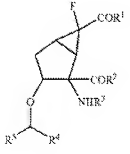
F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-47,50-53,and 56-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No.7,157,594. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim 1 of the patented application are drawn to the following process:

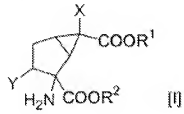
1.A 2-amino-3-alkoxy-6-fluorobicyclo[3.1.0]hexane-2,6-dicarboxylic acid derivative of Formula [I]:



[I]

, whereas the instant claim 1 does teach the following process as shown below:

1. **(currently amended):** A 2-amino-bicyclo[3.1.0]hexane-2,6-dicarboxylic ester ~~derivative~~, or a pharmaceutically acceptable salt thereof ~~or a hydrate thereof~~, represented by formula [I]



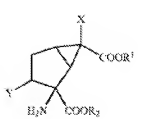
[I]

However, the instant claims differ from the patented application in that the variables R1 and R2, X, and Y of the instant application is broader than the patented application.

Even so, the instant claims teach most parts of variables shown in the patented application and the majority of the claimed limitations are overlapped with each other. Thus, such a limitation can be anticipated; both are commonly shared the same scope of the invention; there is very little difference as to the patentable distinction. In addition, rearranging or combining the dependent claims into the independent claims in the copending application is an obvious variant over the instant claimed invention. Thus, it would have been obvious to the skilled artisan in the art to be motivated to broaden the particular variables in the claims in order to arrive at the same claimed invention as well as extend the coverage of the claimed invention. This is because the skilled artisan in the art would expect such a manipulation to be feasible and successful as guidance shown in the application.

Claims 1-47,50-53,and 56-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.7,381,746. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim 1 of the patented application are drawn to the following process:

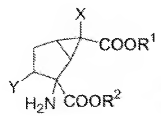
1. A 2-amino-bicyclo[3.1.0]hexane-2,6-dicarboxylic acid derivative, a pharmaceutically acceptable salt thereof or a hydrate thereof, represented by formula [I]



[I]

, whereas the instant claim 1 does teach the following process as shown below:

1. **(currently amended):** A 2-amino-bicyclo[3.1.0]hexane-2,6-dicarboxylic ~~ester derivative~~, or a pharmaceutically acceptable salt thereof ~~or a hydrate thereof~~, represented by formula [I]



[I]

However, the instant claims differ from the patented application in that the variables R1 and R2, X, and Y of the instant application is broader than the patented application.

Even so, the instant claims teach most parts of variables shown in the patented application and the majority of the claimed limitations are overlapped with each other. Thus, such a limitation can be anticipated; both are commonly shared the same scope of the invention; there is very little difference as to the patentable distinction. In addition, rearranging or combining the dependent claims into the independent claims in the copending application is an obvious variant over the instant claimed invention. Thus, it would have been obvious to the skilled artisan in the art to be motivated to broaden the particular variables in the claims in order to arrive at the same claimed invention as well as extend the coverage of the claimed invention. This is because the skilled artisan in the art would expect such a manipulation to be feasible and successful as guidance shown in the application.

Claim Rejections - 35 USC § 102

I. Applicants' argument filed 12/03/09 have been fully considered but they are not persuasive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1-4 under 35 U.S.C. 102(b) as being anticipated clearly by Adam et al (US 6,107,342)

The rejection of Claims 1-4 under 35 U.S.C. 102(b) as being anticipated clearly by Adam et al (US 6,107,342) has been maintained with reasons of record filed on 9/10/09.

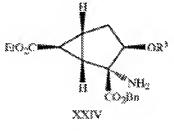
Applicants' Argument

2. Applicants argue the following issues:

i. in view of the revised claims, the presently claimed compounds are inherently anticipated by the compounds disclosed in Adams at col.13 ,lines 30-53 or col. 28 ,lines 17-61 because at least the R^1 and R^2 groups disclosed do not correspond to the claimed compounds; thus, the withdrawal of the rejection under 35 USC 102(b) is requested.

Applicants' arguments have been noted, but the arguments are not found to be persuasive.

Regarding the first argument, the Examiner has noted applicants' argument. However, Adam et al expressly discloses the followings (see col. 13 ,lines 30-53):



XXIV

According to scheme 3 the O-alkylated compounds of general formula I, wherein R^3 is lower alkyl (I-7 and I-8), lower alkenyl (I-9) or benzyl (I-10) can be prepared from compounds of the general formulae XXIII (XXIII-1 with R^3=CH_3; XXIII-2 with R^3=allyl; and XXIII-3 with R^3=benzyl;)and XXIV (XXIV-1 with R^3=CH_3; XXIV-2 with R^3=allyl; and XXIV-3 with R^3=benzyl;)by the methods described above for the preparation of compound I-A.

In this paragraph, the R^1 and R^2 groups in the claims represent ethyl and butyl groups, which are clearly described in the above prior art when a close examination of the paragraph is performed.

Therefore, applicants' argument has been found to be unpersuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taylor Victor Oh/
Primary Examiner, Art Unit 1625
3/28/10